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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,577	02/23/2004	Lung-Ji Chang	58416-00005	9914
45200 7590 06/18/2008 KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			EXAMINER FALK, ANNE MARIE	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 06/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Continuation Sheet (PTOL-303)

At page 3 of the response, Applicants assert that Schlom does not disclose a tumor cell composition consisting essentially of a tumor cell modified to express B7.2 and at least one additional immune modulator. Applicants assert that the compositions disclosed by Schlom all require expression of an exogenous tumor associated antigen which has been introduced into the host cell in a recombinant vaccinia virus. Applicants allege that the tumor associated antigen of Schlom is not an endogenous antigen. Applicants further allege that the instant claims use the phrase “consisting essentially of” and therefore Schlom does not disclose the identical composition as the instant claims because the instantly claimed invention does not require an exogenously introduced tumor associated antigen in order to induce an immune response. Applicants are arguing limitations that are not in the claims. There is nothing in the claims that excludes a tumor cell that contains exogenous elements. The claims cover any tumor cell at all, as long as it is modified to express a B7-2 protein and at least one additional immune modulator. Accordingly, Schlom et al. not only discloses, but also claims, a composition **consisting essentially of** a tumor cell modified to express a B7-2 protein and at least one additional immune modulator.

At page 4 of the response, Applicants allege that Schlom does not disclose the identical invention as instantly claimed. On the contrary, for the reasons discussed above and below, and further reasons of record, Schlom et al. does disclose a composition **consisting essentially of** a tumor cell modified to express a B7-2 protein and at least one additional immune modulator. This is the identical invention.

At page 4 of the response, Applicants allege that the instant claims exclude an exogenously introduced tumor antigen. Applicants are incorrect because the instant claims require a composition consisting essentially of a tumor cell modified to express a B7-2 protein and at least one additional immune modulator. Applicants are reminded that the term “tumor cell,” as recited in the instant claims, includes everything that may be expressed in or on a tumor cell and therefore does not exclude natural tumor cell components, such as a tumor-associated antigen, or exogenous components, such as an

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exogenously introduced tumor-associated antigen. Tumor cells comprise a plethora of molecular components that make up the cell. Accordingly, the tumor cell may comprise a variety of endogenous and exogenous elements. According to the claim, **any tumor cell** may be used, as long as it is modified to express a B7-2 protein and at least one additional immune modulator. Contrary to Applicant's allegation the tumor cell may indeed comprise other exogenous elements. Given “the consisting essentially of” language, the scope of the claim is limited to the specified materials “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis original). In other words, the claimed composition does not include other cell types or other agents that would materially affect the basic and novel characteristics of the composition. The tumor cell itself can comprise anything at all, as long as it includes a B7-2 protein and at least one additional immune modulator. Moreover, Applicants are reminded that the guidance in the MPEP notes that, for the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See MPEP § 2111.03. Schlom et al. does disclose and claim, a composition consisting essentially of a tumor cell modified to express a B7-2 protein and at least one additional immune modulator. See, for example, Claim 5. The composition of Claim 5 does not comprise anything other than a tumor cell modified to express a B7-2 protein and at least one additional immune modulator, and therefore the composition does indeed **consist essentially of** said tumor cell, as set forth in the present claims. Nothing more is required.

Accordingly, the rejection is maintained for reasons of record.